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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/491,624	01/26/2000	Carlos Picornell Darder	4948-2PCIP	8816

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EXAMINER

PULLIAM, AMY E

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 02/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/491,624

Applicant(s)

DARDER, CARLOS PICORNELL

Examiner

Amy E Pulliam

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 15-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 15-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 13
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Receipt is acknowledged of the Corrected Filing Receipt, the Request for a CPA, and the Preliminary Amendment B, received October 9, 2001.

Applicant's amendment to the claims, changing the transitional language from "comprising" to "consisting essentially of" has overcome the previous prior art rejections. Applicant's arguments with respect to the claims have been considered but are moot in view of the following new ground(s) of rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-13, and 15-34 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,132,771 to Depui *et al.*. Depui *et al.* disclose an oral pharmaceutical dosage form comprising a proton pump inhibitor (abstract). More specifically, Depui *et al.* teach that the proton pump inhibitor can be selected from omeprazole, lansoprazole, pantoprazole, pariprazole, and leminoprazole (c 5-6). Additionally, Depui *et al.* teach that the core material for their composition is a seed layered with the proton pump inhibitor (c 8, l 48-50). Depui *et al.* also teach that the seeds can be made of different materials, including sugars (c 8, l 57). Depui *et al.* also teach that the proton pump inhibitor can be mixed with other components prior to layering on the seeds, wherein the components can include binders, surfactants, disintegrating agents, and fillers (c 9, l 1-5). The binder can be selected from HPM, HPMC, CMC, PVP, sugars and starches (c 9, l 3-6). The alkaline substance can be selected from sodium potassium, calcium, magnesium, and aluminum salts of phosphoric acid, carbonic acid, citric acid, and other weak acids, as well as magnesium oxide substances, and other substances normally used in antacid compositions (c 9, l 27-42). The surfactant can be sodium lauryl sulfate (c 9, l 10). Depui *et al.* also teach that the seeds have a size between 0.1 and 2 mm, which equals 100 to 2000 micrometers (c 8, l 62). Most importantly, Depui *et al.* teach that their formulation does not necessarily include a spacing layer between the coated seed and an enteric coating. Depui *et al.* teach that a middle, separating layer is optional, as the enteric coating can be applied directly to the coated core (c 9, l 46-50 and c 10, l 41-43). The enteric coating layer can be selected from HPMCP, methacrylic acid polymers, HPMC acetate succinate, shellac, and others (c 1, l 46-53). The enteric

coating layer can also comprise a plasticizer such as PEG or cetyl alcohol (c 10, l 58-60). Therefore, the teachings of Depui *et al.* anticipate the limitations of applicant's instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-13, and 15-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Depui *et al.*, as discussed above, and in view of the following comments. Depui *et al.* is discussed above as teaching an oral pharmaceutical composition comprising a proton pump inhibitor and an enteric coating. Depui *et al.* does not necessarily state that there can be no separating layer between the enteric coating layer and the coated seed. However, Depui *et al.* do teach that one of their embodiments is to coat the seed with the active layer, and then directly coat that with an enteric layer. One of ordinary skill in the art would have been motivated to make an oral composition comprising an inert core, an active coating, and an enteric coating, without the presence of a separating layer, based on the teachings of Depui *et al.*. The expected result would be a successful composition for the treatment of gastrointestinal disorders. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

aep
February 19, 2002


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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